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| APPLICATION NO.                                  | F          | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|--|------------|------------|----------------------|---------------------|------------------|--|
| 09/836,073                                       | 04/16/2001 |            | Asim Dasgupta        | 220002054822        | 5718             |  |
| 25225  | 7590       | 10/14/2005 |                      | EXAMINER            |                  |  |
| MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE |            |            |                      | MCGARRY, SEAN       |                  |  |
| SUITE 500  | ET CENT    | KE DRIVE   |                      | ART UNIT            | PAPER NUMBER     |  |
| SAN DIEGO  | O, CA 92   | 2130-2332  | 1635                 |                     |                  |  |

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)  |                             |
|--|--|---|-----------------------------|
| Advisory Action  | 09/836,073   | DASGUPTA ET AL.                                       |                             |
| Before the Filing of an Appeal Brief   | Examiner   | Art Unit  |                             |
|  | Sean R. McGarry  | 1635  |                             |
| The MAILING DATE of this communication app   | ears on the cover sheet with the   | correspondence addre                                  | ess                         |
| THE REPLY FILED 21 September 2005 FAILS TO PLACE TH  | IIS APPLICATION IN CONDITION   | FOR ALLOWANCE.  |                             |
| <ol> <li>The reply was filed after a final rejection, but prior to or of<br/>this application, applicant must timely file one of the followalces the application in condition for allowance; (2) a National and a Request for Continued Examination (RCE) in compliant time posicide;</li> </ol> | owing replies: (1) an amendment, at otice of Appeal (with appeal fee) in | ffidavit, or other evidence<br>compliance with 37 CFF | e, which<br>R 41.31; or (3) |

| this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3  |
|--|
| a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following   |
| time periods:  |
| a) The period for reply expiresmonths from the mailing date of the final rejection.  |
| b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  |
| Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).   |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  NOTICE OF APPEAL |
| 2. The Notice of Appeal was filed on A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).   |
| AMENDMENTS  2. M. The managed amount (a) filled often a final rejection, but arise to the data of filling a bejot will get be entered because  |
| 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below);  |
| (c) ☐ They raise the issue of new matter (see NOTE below),  (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or   |
| (d) They present additional claims without canceling a corresponding number of finally rejected claims.  NOTE: (See 37 CFR 1.116 and 41.33(a)).  |
| 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  |
| 5. Applicant's reply has overcome the following rejection(s):  |
| 6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  |
| 7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.   |
| The status of the claim(s) is (or will be) as follows: Claim(s) allowed:   |
| Claim(s) objected to:  |
| Claim(s) rejected: 1-7 and 9-12.   |
| Claim(s) withdrawn from consideration: <u>20-24</u> .<br>AFFIDAVIT OR OTHER EVIDENCE   |
| 8.  The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will <u>not</u> be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary an was not earlier presented. See 37 CFR 1.116(e).   |
| 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).   |
| 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.  REQUEST FOR RECONSIDERATION/OTHER  |
| 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  See Continuation Sheet.  |
| 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s).  |
| 13. Other:   |
|  |
| Seán R McGarry Primary Examiner  |
| Art Unit: 1635   |

U.S. Patent and Trademark Office PTOL-303 (Rev. 7-05)

Continuation of 11. does NOT place the application in condition for allowance because: Applicants arguments have been considered but they do not overcome the rejection of record even in view of the proposed amendments. Applicant asserts that one in the art would be led to the recited subgeneric formula by the specification. It is the examiners position that one in the art would clearly not be led to the formula which, for example, includes Q at position A4, A12 or A 17, since the specification clearly states that the peptides of their invention are required to contain acidic amino acids at those positions. Any assertion that one would be led to put a Q at any of those positions as a prefered embodimant is contrary to the specification (see paragraph 14). Applicant points to paragraph 33 to assert that 701 has a Q in the recited location. The specification makes no such disclosure at 33, but at paragraph 53 it is shown that 701, with Q in the cited location, does not work. Applicants proposed claim also includes the insertion of polar neutral at A14 where the specification asserts that in certain embodiments where there is no further discussion of what those certain embodiments might be and applicants arguments do not point to where such disclosure might be, for example. How is one led to such certain embodiments? Applicant argues each position in terms of prefered embodiments but some positions that are included in the formula include amino acids that have been shown to reduce the effectiveness of the peptides or are not prefered embodiments of those positions (positions A1, A2, and A3, for example). Applicant appear to argue to individual position individually, but has not shown how the discussion of these positions would clearly lead one in the art to the specific formula now recited where the specific formula is not itself specifically discosed in the specification as originally filed. It is noted that even if applicants amendments and arguments were convincing, the amendment would still not be entered since, once the compounds of the invention where found allowable, the methods would be rejoined. Such a rejoinder would cause new considerations of enablement, for example .

## Notice of Non-Compliant Amendment (37 CFR 1.121)

| Application No. | Applicant(s)    |  |
|-----------------|-----------------|--|
| 09/836,073      | DASGUPTA ET AL. |  |
| Examiner        | Art Unit        |  |
| Sean R. McGarry | 1635            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on <u>21 September 2005</u> is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

| , <del>-,   -   -   -   -   -   -   -   -   -  </del>   |                           |
|---|---------------------------|
| THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:  1. Amendments to the specification:  A. Amended paragraph(s) do not include markings.  B. New paragraph(s) should not be underlined.  C. Other  |                           |
| <ul> <li>2. Abstract:</li> <li>A. Not presented on a separate sheet. 37 CFR 1.72.</li> <li>B. Other</li> </ul>  |                           |
| <ul> <li>3. Amendments to the drawings:</li> <li>A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Shee "Annotated Sheet" as required by 37 CFR 1.121(d).</li> <li>B. The practice of submitting proposed drawing correction has been eliminated. Replacement drashowing amended figures, without markings, in compliance with 37 CFR 1.84 are required.</li> <li>C. Other</li> </ul>  |                           |
| <ul> <li>✓ 4. Amendments to the claims:</li> <li>☐ A. A complete listing of all of the claims is not present.</li> <li>☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)</li> <li>☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual sof each claim cannot be identified. Note: the status of every claim must be indicated after its conumber by using one of the following status identifiers: (Original), (Currently amended), (Cance (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended)</li> <li>☐ D. The claims of this amendment paper have not been presented in ascending numerical order.</li> <li>☐ E. Other: Claim 1 does not match the text of the previous version (SEQ ID is missing). Claim 11 is as being "previously presented" but appears to be "amended".</li> </ul> | status<br>claim<br>eled), |

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <a href="http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf">http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf</a>.

## TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

- 1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.
- 2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

<u>Extensions of time</u> are available under 37 CFR 1.136(a) <u>only</u> if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

## Failure to timely respond to this notice will result in:

**Abandonment** of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.